I. TITLE: External Panel Peer Review of Approach for Characterizing Uncertainty at Lower $PM_{2.5}$ Concentrations

II. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA COR):

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III. PERIOD OF PERFORMANCE:

Duration: Upon CO approval through September 15, 2019

IV. BACKGROUND:

The Agency has employed a number of techniques for characterizing the magnitude, distribution and uncertainty associated with $PM_{2.5}$-related health effects. For example, when describing the uncertainty associated with PM-related mortality, the Agency has drawn upon the results of the 2006 PM Expert Elicitation, wherein 12 experts described the shape and magnitude of the concentration-response relationship and the probability of a threshold (or safe level) below which PM-related effects were not expected to occur. All but one expert reported that the PM-mortality relationship was log-linear without a threshold; one expert believed a threshold may exist at relatively low $PM_{2.5}$ levels.

Beginning in 2010, the Agency began reporting the number of PM-related premature deaths estimated to occur above and below the Lowest Measured Levels (LMLs) of the two long-term cohort studies used to quantify PM mortality risk. In this analysis, the Agency noted that it was less confident in PM-related effects estimated to occur below these LMLs. Regulatory Impact Analyses reporting benefits this way find that most avoided deaths occur above the LMLs of each study. More recently, the Agency has begun reporting the number of avoided (or incurred) PM-related deaths at annual mean PM concentrations that correspond to the levels observed in the American Cancer Society long-term cohort study. Following this approach, the Agency indicates it is most confident in results occurring at model-predicted $PM_{2.5}$ levels that correspond to the mass of the PM air quality distribution observed in the epidemiological study used to quantify risk.

Researchers continue to develop new quantitative techniques for characterizing the uncertainty associated with effects estimated at lower PM levels. This work assignment (WA)

directs the Contractor to coordinate and facilitate a panel peer review of two new quantitative techniques for identifying the portion of a concentration-response relationship below which we begin to lose confidence in the magnitude of the effect.

V. STATEMENT OF WORK (SOW):

The Contractor shall conduct the following tasks in accomplishing the objective of this work assignment. All work to be done under this work assignment shall be in compliance with the EPA *Science and Technology Policy Council Peer Review Handbook* (Fourth Edition, EPA/100/B-15/001, 2015), available online at: http://www.epa.gov/osa/peer-review-handbook-4th-edition-2015.

Task #1: Develop Work Plan

The Contractor shall develop a work plan for this WA, including a cost estimate. The Contractor shall submit the proposed work plan no later than twenty (20) days following approval and receipt of this WA. In addition, the Contractor shall provide monthly progress reports to be submitted with the invoice in the manner described in this contract.

Task #2: Identify Experts

The Contractor shall first consult the technical memorandum accompanying this manuscript to review the two proposed approaches for characterizing uncertainty at lower $PM_{2.5}$ concentrations. The Contractor shall identify between fifteen to twenty (15-20) experts in the fields of epidemiology, biostatistics, air quality modeling and clinical medicine who publish actively in one or more of these fields. Candidate panelist/reviewers may hold positions in academic, non-profit, consulting, or government institutions, as long as they can demonstrate the following expertise. The candidate panelist/reviewers shall have scientific credentials equivalent to a Ph.D. and shall be regarded as experts in their respective fields. Expertise shall be judged by authorship on original publications and/or reviews in scientific journals in the areas of expertise identified above. Candidate panelist/reviewers may also be judged by other measures of expertise including professional accomplishments and membership in professional societies to the extent that this peer review represents a Highly Influential Scientific Assessment (HISA), then the Contractor shall arrange for public input on potential reviewers, per the EPA *Science and Technology Policy Council Peer Review Handbook* (Fourth Edition, EPA/100/B-15/001, 2015).

The Contractor shall present this list of fifteen to twenty experts, along with bio-sketches, to the WA COR. The Contractor shall screen these individuals for Conflict of Interest (COI) and appearance of bias issues, as identified in the EPA Science and Technology Policy Council Peer Review Handbook (Fourth Edition, EPA/100/B-15/001, 2015). The WA COR will identify any individuals from this list who do not have the appropriate expertise or have potential conflicts of interest. Having removed the ineligible experts, the Contractor shall select between six to nine (6-9) experts to serve on the peer review panel. The final selection of reviewers shall be the responsibility of the Contractor. The Contractor shall, to the extent feasible, establish a panel balanced according to subject matter expertise.

The selected experts need to be available to attend a pre-meeting conference call, the panel meeting itself, and prepare a written response to the charge questions. When eliciting the participation of each expert, the Contractor is authorized to offer compensation in the form of an honorarium.

The Contractor shall identify one member of the panel to serve as the chair for the panel. The chair will have the additional duties of working with the Contractor during the meeting to guide the discussion, providing leadership to the panel to accomplish their charge, and ensuring all focus areas are covered during the independent panel discussions. Selection of the chair shall be at the sole discretion of the Contractor, but the Contractor may solicit input from all selected reviewers. The chair shall be identified using the following criteria:

- Expertise on all or most of the focus areas to be covered
- Demonstrated experience of leading peer review discussions amongst a group of individuals
- Availability of any time commitments beyond those of the other reviewers

Deliverables:

2.1 Draft list of experts
2.2 Final list of experts
2.3 Selection of panel chair

Task #3: Distribute Pre-Meeting Materials and Convene Conference Call

Following the selection of six to nine (6-9) experts, the Contractor shall provide electronic materials to all reviewers. Materials shall consist of the document to be reviewed, the charge for reviewers (including charge questions), and any logistical information for the in-person panel meeting.

No later than one week before the panel review, the Contractor shall convene a conference call for all experts and appropriate EPA staff. The purpose of this meeting shall be to review the meeting agenda, allow EPA technical staff to provide a short summary of the document, describe the scope of the review, and to allow experts to ask questions and obtain clarification from EPA. This conference call shall be facilitated by the Contractor and the panel chair.

Deliverables:

3.1 Share materials with reviewers
3.2 Convene pre-meeting conference call

Task #4: Manage, Conduct, and Support of Panel Review Meeting and Meeting-Related Travel

The Contractor shall manage, conduct and support a one- (1-) day panel review meeting at the U.S. EPA facility in Research Triangle Park, North Carolina. The meeting shall include time for a brief presentation by EPA technical staff with sufficient time for reviewers to ask clarifying questions. The remainder of the meeting time shall be for discussion between panel

members in any format as the Contractor sees fit. The Contractor shall arrange transportation, lodging, per diem, and logistical support for the selected experts, as required. The Contractor shall arrange appropriate compensation (e.g., honoraria) for the time and effort of these experts.

The Contractor shall prepare a meeting agenda and submit to the WA COR for review prior to the pre-meeting conference call. The Contractor may confer with the selected panel chair in developing the agenda. EPA technical staff will only present factual and content-based information about the work that EPA has conducted and will not respond or provide personal opinions or provide any information that might have the appearance of biasing the independence of the panel reviewers.

The Contractor shall coordinate all logistical and/or technological details of the meeting. EPA will provide a contact at the RTP facility for the Contractor to consult with about location-specific information. The RTP facility typically has available projectors, video conferencing, conference lines, and WiFi, but are subject to availability. Any other equipment needed to conduct the meeting shall be the responsibility of the Contractor.

The Contractor shall facilitate the one- (1-) day panel review meeting. At the beginning of the meeting, the Contractor shall indicate to the panel that EPA is seeking the individual opinions of the reviewers and not a consensus of the group. The Contractor shall also remind the reviewers of all policies about the external nature and independence of this review from EPA, and/or bias, as outlined in the EPA Science and Technology Policy Council Peer Review Handbook (Fourth Edition, EPA/100/B-15/001, 2015). The Contractor may arrange for the panel chair to lead sessions, as appropriate.

The Contractor shall be responsible for taking notes during the meeting for inclusion in the final peer review report.

Deliverables:

4.1 Panel Review meeting
4.2 Transportation, lodging, and logistical support for reviewers
4.3 Meeting agenda
4.4 Meeting notes

Task #5: Issue Final Report

The individual reviewers shall provide a written response to the charge questions. Following the panel review meeting, the Contractor shall receive, compile, and deliver to the WA COR the expert responses to the charge questions in the form of a report. The WA COR shall review the expert comments and the Contractor shall follow up with the experts about any clarification questions by EPA technical staff. The Contractor shall review the responses to ensure that the experts have fulfilled their responsibilities under their agreement with the Contractor. The Contractor shall share this draft report with each expert for review and comment before finalizing the report for EPA.

The individual experts' responses shall be compiled into a single electronic document with the following format:

- Introduction, background, identify/summarize reviewers and expertise
- Describe the process to arrive at the final report
- Summary of the meeting that characterizes the discussions (not meeting minutes)
- Summary/synthesis of the reviewers' responses to charge questions
- Peer reviewers' responses sorted by charge questions
- Charge that was given to reviewers
- CVs for all reviewers

The Contractor shall not edit or alter any comments but shall format the comments for consistency. The Contractor shall also share the responses to charge questions to the panel chair for means of ensuring that all questions are answered with the appropriate level of technical explanation.

Deliverables:

5.1: Draft report
5.2: Final report

VI. REPORTING REQUIREMENTS:

All reports shall be in accordance with contract specifications. The Contractor shall submit work products in electronic as well as hard copy form. In addition, the Contractor shall deliver to the WA COR each draft and final report in electronic format that is readable by OAQPS's windows-based word-processing (Microsoft Word 2016), graphics (Microsoft PowerPoint 2016), spreadsheet (Excel 2016), and database (Access 2016) programs.

III. DELIVERABLES:

The Contractor shall adhere to the following schedule:

Task	Deliverable	Delivery Schedule
1	Cost estimate	20 days after effective date of WA
2	List identifying experts	2 months after effective date of WA
3	Facilitate travel	3 months after effective date of WA
4	Facilitate peer review	To be determined
5	Final report	To be determined